

REMARKS

Claims 4 and 5 are pending in the present application, and remain unchanged.

I. Rejection of Claims 4 and 5 Under 35 U.S.C. § 103 in View of United States Patent No. 6,281,192 to Leahy *et al.*

Claims 4 and 5 have been rejected under 35 U.S.C. § 103 as obvious in view of Leahy *et al.* ("Leahy"), United States Patent No. 6,281,192. Applicant respectfully traverses.

As an initial matter, a *prima facie* case for obviousness has not been established. First, the Office Action has acknowledged that Leahy does not teach each and every element of the pending claims. The presently pending claims recite a composition having a polyhexamethylene biguanide (PHMB) concentration of 0.01% to 5% by weight, which is much higher than the 15 ppm taught by Leahy.

Second, there is no motivation to modify the teachings of Leahy in the manner suggested in the Office Action, *i.e.*, by increasing the amount of PHMB taught by Leahy from 15 ppm to the amounts recited in claim 4 (0.01% to 5%, *i.e.*, 100 ppm to 50,000 ppm). Leahy is directed to an ophthalmologic composition for the treatment of eye conditions. Leahy teaches that a very small amount of preservative (up to 15 ppm) may be optionally present; PHMB is one of many possible compounds that can be used as a preservative (Leahy, col. 8, lines 59-67).

In contrast, the present claims recite a composition useful as a hard surface cleaning agent. To that end, the PHMB is an antimicrobial agent that is desirably deposited on, and kept in contact with, the target hard surfaces as part of the cleaning process. The mucin, an anionic polymer, is used as a carrier and linker for the PHMB, facilitating the adhesion of the PHMB to the hard surface that is to be cleaned. Thus, the PHMB is optimally in amounts sufficient to achieve these goals, *i.e.*, amounts significantly greater than 15 ppm.

However, there is no teaching or suggestion in Leahy to include PHMB in any amounts greater than 15 ppm. Despite the Office Action's statement that the amounts of PHMB recited in the pending claims could be discovered by routine experimentation, a cited reference must suggest the combination and selection of parameters for the

composition in order to meet the obviousness standard. *In re O'Farrell*, 853 F.2d 894, 903, 7 U.S.P.Q.2d 1673, 1681 (Fed. Cir. 1988). Here, it clearly does not.

There is no motivation to increase the amount of PHMB taught by Leahy by at least sixfold, *i.e.*, from 15 ppm up to 100 to 50,000 ppm. Such an increase would render Leahy unsatisfactory for its intended purpose. MPEP § 2143.01. Leahy teaches a composition for treating eye conditions, while the present claims are directed to a composition for cleaning hard surfaces. Were the example in Leahy to be modified in the manner suggested by the Office Action, *i.e.*, increasing the biguanide from 15 ppm up to 100 to 50,000 ppm, such a modification would render Leahy unsatisfactory for its intended purpose as a composition for treating the delicate tissues of the human eye. A high concentration of preservative would be expected to have adverse effects on a patient's eyes, and thus, such a marked increase in a potentially irritating component in an eye composition clearly would not be contemplated within the parameters of routine experimentation.

Finally, even if one of ordinary skill in the art were motivated to modify the composition taught by Leahy in the manner suggested in the Office Action (which Applicant maintains is not the case), there would certainly be no expectation of success in such a modification. Leahy teaches that the PHMB is necessary only in tiny quantities as a *preservative* in an eye composition. Clearly, to one of ordinary skill in the art an increase of at least sixfold (and up to three thousandfold) of a preservative would be unnecessary, and furthermore, would be expected to have an adverse effect on the eyes and thus fail as an eye composition.

Thus, the present claims are not obvious in view of Leahy, and accordingly, Applicant respectfully submits that this rejection has been overcome and should be withdrawn.

II. Rejection of Claims 4 and 5 Under 35 U.S.C. § 103 Based on United States Patent No. 6,277,365 to Ellis or JP 2000-109892 to Tetsuhisa

Claims 4 and 5 have been rejected under 35 U.S.C. § 103 as obvious over United States Patent No. 6,277,365 to Ellis ("Ellis") or JP 2000-109892 to Tetsuhisa ("Tetsuhisa"). Applicant respectfully traverses.

Like Leahy, Ellis and Tetsuhisa are both directed to compositions in the ophthalmologic arts. Both are directed to compositions for treating contact lenses or the surface of an eye. Both Ellis and Tetsuhisa teach that PHMB, when present, is desirable at low concentrations and has antimicrobial or germicidal properties.

The Office Action acknowledges that the amount of PHMB taught by Test Solution 2 of Ellis (15 ppm) is not within the ranges recited in the present claims. (Office Action, p. 4). Similarly, the Office Action also acknowledges that Tetsuhisa does not teach PHMB in the ranges recited in the presently pending claims, as this reference teaches that the preferred concentration of PHMB is only 0.00001 to 0.001% (0.1 ppm to 10 ppm) (Tetsuhisa, Paragraph [0010]).

The Office Action states that the ranges recited herein are obvious in view of Ellis or Tetsuhisa, and cites *In re Aller*, 220 F.2d 454, 105 U.S.P.Q. 233 (C.C.P.A. 1955) for the proposition that it is not inventive to discover optimum or workable ranges by routine experimentation. However, the ranges of PHMB recited in the pending claims would not qualify as an optimum or workable range as taught by Ellis or Tetsuhisa, and could not be achieved by routine experimentation of one of ordinary skill in the art.

It would simply not have been obvious to one of ordinary skill in the art of hard surface cleaners to increase the amount of PHMB from the amounts taught by a reference directed to compositions for treating contact lenses. First, because Ellis and Tetsuhisa are directed to compositions that come into contact with the eye, one of ordinary skill in the art would simply not be motivated to look to their teachings in developing a hard surface cleaner.

Next, even if one of ordinary skill in the art were motivated to view such references (which Applicant maintains is not the case), there would be no motivation in either of the references to increase the amounts of PHMB taught therein to the levels recited in the pending claims. Ellis teaches that PHMB is used as a disinfectant for a contact lens (Ellis, col. 6, lines 25-26). Tetsuhisa teaches that it can be a germicide (Tetsuhisa, Paragraph [0010]). However, one of ordinary skill in the art would not be motivated to increase the amounts of PHMB taught by either Ellis or Tetsuhisa to arrive at the amounts presently claimed, because it would be expected that high amounts of a

disinfectant or germicide might hurt the delicate surface of eyes, or destroy the fragile and thin material of contact lenses.

Moreover, even if one of ordinary skill in the art were motivated by the teachings of Ellis or Tetsuhisa to modify the composition taught in the manner suggested in the Office Action (which Applicant maintains is not the case), there would certainly be no expectation of success in such a modification. Ellis and Tetsuhisa both teach that PHMB is present only in tiny quantities in an eye composition. Clearly such an increase in the PHMB would be expected to have an adverse effect on the eyes and thus fail as an eye composition.

In fact, further to the above arguments, Tetsuhisa *teaches away* from the present claims, because they teach that the PHMB should be present only in small amounts in the eye or on the contact lens. The present invention demonstrates an unexpected results over the art: namely, that the PHMB, when present in sufficient quantities, successfully binds with the mucin so that it adheres to the hard surface for longer than expected, thus prolonging the antimicrobial effect. *See, e.g.,* Examples I through III of the present disclosure, which demonstrate that the combination of mucin and PHMB in the amounts recited in the claims unexpectedly leads to a stronger binding of PHMB to the hard surface to be cleaned, and thus superior results.

In contrast, Tetsuhisa teaches that the germicide should desirably be present in concentrations of 0.00001% to 0.1%, “so that the washing activity of an enzyme may not be checked with a high-concentration germicide” (Abstract of Tetsuhisa, Paragraph [0010]). To that end, Tetsuhisa teaches that in the case of PHMB, the especially desirable concentration is only 0.00001 to 0.001% (0.1 to 10 ppm), no higher. Tetsuhisa thus teaches away from the present claims, because it teaches that the PHMB should be kept at a low level so as not to hinder the washing activity of the enzyme in the eye composition.

For at least these reasons, the present claims are not obvious in view of Ellis or Tetsuhisa. Accordingly, Applicant respectfully submits that this rejection has been overcome and should be withdrawn.

III. Provisional Double Patenting Rejection

The Examiner has issued a provisional rejection of pending claims 4 and 5 based on the judicially-created doctrine of obviousness-type double patenting, as being unpatentable over claims 1 and 2 of United States Patent No. 6,479,044. Applicant respectfully requests that this issue be held in abeyance until the presently pending claims are otherwise indicated to be allowable. At that time, Applicant will offer to file a Terminal Disclaimer if appropriate.

In view of the above remarks, it is believed that the claims are now in condition for allowance, early notice of which is earnestly solicited.

If any outstanding issues remain, the Examiner is invited to contact Applicant's undersigned attorney at the telephone number below.

Respectfully submitted,

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